IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

U.S. ex rel. SCHUMANN, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
ASTRAZENECA PLC, et al.	:	NO. 03-5423

M E M O R A N D U M A N D O R D E R

Ditter, J. October 13, 2010

This case involves a whistleblower's claims that two pharmaceutical companies violated federal and state false claims statutes by entering into fraudulent agreements to sell their brand-name drugs. It comes before me on motions to dismiss the fourth amended complaint by defendants E.I. du Pont de Nemours and Company, DuPont Pharmaceuticals Company, and Bristol-Meyers Squibb Company (collectively "BMS") (Doc. 172) and defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AZ") (Doc. 174).

The relator, Karl Schumann, alleges in this *qui tam* action that the defendants paid disguised, undisclosed rebates to a purchaser of their products so that the actual price of those products was misrepresented to the government and the government overpaid for them. This memorandum is filed to explain the reasons for my order of September 30, 2010, granting BMS' motion to dismiss the relator's claims with prejudice and denying AZ's motion to dismiss the relator's claims.

I. FACTUAL BACKGROUND

The relator makes the following allegations in his fourth amended complaint that are relevant to this opinion:

The relator is a registered pharmacist and was the vice-president of pharmaceutical contracting for Medco from December 1999 to January 2003, during which time he alleges he obtained knowledge of the defendants' false claims and kickbacks. Medco has been one of the largest pharmacy benefit managers and mail-order pharmacies in the country. Medco negotiates with drug manufacturers and retail pharmacies to obtain discounts on prescription drugs for its health plans and has considerable leverage with drug manufacturers in deciding which of their drug products are dispensed in their retail pharmacy networks and mail-order pharmacies. Medco has provided prescription drug services to various federal and state government plans. The defendants, BMS and AZ, manufactured, marketed, and sold drug products in Pennsylvania and throughout the United States. Coumadin is a brand-name drug manufactured by BMS. Prilosec and Nexium are brand-name drugs manufactured by AZ. Under certain federal laws, drug manufacturers who participate in government programs must price their products so that the government will not pay more for a drug than the best price for which the manufacturer sells that drug to other purchasers.

The relator alleges that BMS and AZ violated federal and state false claims statutes in two ways. First, BMS and AZ entered into sham contracts with Medco to induce it to purchase and dispense to government plan patients the defendants' brand-name drugs, rather than the equivalent generic drugs, in violation of anti-kickback laws, causing false claims[1] for reimbursement of those drugs to be submitted to government plans. Second, BMS and AZ

[1] Overstated, but false in the sense that they were based on the alleged kickback fraud between AZ and Medco.

submitted false best price reports for the defendants' brand-name drugs, causing false claims[2] for rebates of Medicaid and 340B expenditures to be submitted to the government. The alleged sham contracts between BMS and Medco included rebates and data fees from 1997 through 2003 related to the drug Coumadin, and the alleged sham contracts between AZ and Medco included rebates, service fees, disease-management fees, and unrestricted educational grants from 1996 through 2003 related to the drugs Prilosec and Nexium.

With respect to the relator's claims against BMS, he alleges that "he regularly discussed with his Medco colleagues the highly confidential dealings with the BMS defendants that had occurred prior to his employment with Medco wherein he learned of the [fraud]." (Fourth Am. Compl. ¶ 54.) He also alleges that he was involved in contract negotiations with BMS on April 24, 2001, and January 25, 2002, to discuss Coumadin rebate agreements. (*Id*. ¶¶ 55, 86-87.)

With respect to the relator's claims against AZ, the relator alleges that "[b]ut for the [AZ] Defendants' Fraudulent Kickbacks . . . to Medco . . . to induce the referral of the [AZ] Defendants' Prilosec and Nexium, the Government would not have paid millions of dollars for Prilosec and Nexium prescriptions" through government-health plans and programs. (*Id*. ¶ 115; *see also id.* ¶¶ 109, 113, 114, 120, 134, 239-243.) The relator also alleges that AZ "submitted false quarterly statements to [the government] of its Best Prices on [Prilosec and/or Nexium] . . . to reduce improperly [its] rebate obligations to the States under the Best Price Program." (*Id.* ¶ 141; *see also id*. ¶¶ 151, 163, 171, 184, 187, 193, 204, 214, 221, 229, 237.) He alleges that AZ's "false quarterly statements of the Best Prices on [Prilosec and Nexium] caused the States to

[2] Understated, but false in the sense that they were based on the alleged false best price reports submitted by AZ.

submit false and inflated submissions to the Federal Government for reimbursement of Medicaid expenditures." (*Id*. ¶ 141.)

The relator filed this *qui tam* action under federal and state statutes that allow private persons with knowledge of past or present fraud against the government to bring claims on its behalf. 31 U.S.C. § 3730. In his fourth amended complaint, the relator brought four counts each against BMS and AZ for making or causing false claims or false statements and conspiracy to commit acts in violation of the federal False Claims Act ("FCA"), 31 U.S.C. § 3729.[3] The relator also brought thirteen similar counts against BMS and AZ under various state false claim statutes.[4] Both BMS and AZ filed motions to dismiss and oral argument on the motion was held before me.

II. PARTIES' CONTENTIONS

BMS contends that the fourth amended complaint must be dismissed because the relator's allegations are based on prior publicly disclosed allegations or information and that the relator is not an "original source" as defined by the FCA. In the alternative, BMS contends that the complaint must be dismissed pursuant to Rule 12(b)(6) for the relator's failure to satisfy the pleading requirements of Rule 9(b) and Rule 8(a). AZ likewise contends that the complaint must be dismissed under Rule 12(b)(6) for relator's failure to satisfy the pleading requirements of Rule

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[3] On May 20, 2009, the FCA was amended, but with one exception not applicable here, the amendments are prospective only. Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 31 U.S.C. § 3729 (2009). Therefore, I refer to the substantive provisions of the FCA prior to enactment throughout this opinion, just as the parties did in their submissions. Both the kickback claims and best price report claims form the basis for all of the relator's counts under FCA provisions. 31 U.S.C. § 3729(a)(1)-(3), (7).

[4] The state false claims statutes on which the relator relies are modeled on the federal FCA and are consistently interpreted with that statute. *See, e.g. United States ex rel. Bogart v. King Pharm.,* 414 F.Supp. 2d 540, 543 (E.D. Pa. 2006); *United States v. Johnson Controls, Inc.,* 457 F.3d 1009, 1021 (9th Cir. 2006); *Int'l Game Tech, Inc. v. Second Judicial Dist. Ct.,* 127 P.3d 1088, 1101 (Nev. 2006).

9(b) and Rule 8(a). AZ argues that the relator has failed to plead the details of any individually submitted false claim, and/or false claims submitted by the states, or any facts demonstrating that any state's submissions or AZ's best price reports were false. BMS and AZ also contend that some claims are barred by the statute of limitations and that dismissal should be with prejudice because any amendments to the complaint would be futile.[5]

III. DISCUSSION

A. Relator's Claims Against BMS

BMS asks for dismissal of the relator's claims against it for lack of subject matter jurisdiction under Rule 12(b)(1) because they are barred by the FCA's existing information limitation, 31 U.S.C. § 3730(e)(4)(A). BMS argues that the claims are based upon allegations or transactions that were publicly disclosed before the relator asserted them in this action and that the relator is not an original source because he fails to allege the necessary "direct and independent" knowledge. I agree. The relator's claims against BMS are substantially similar to numerous prior public disclosures, and based on his limited allegations in the fourth amended complaint, the relator cannot be deemed an original source.

1. Standard of Review for Jurisdictional Challenges

Before addressing the merits of a case, a court must resolve any jurisdictional challenge. *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998). Here, BMS asserts a factual challenge to subject matter jurisdiction under Rule 12(b)(1).[6] (BMS Mot. 6-30; Oral

[5] I shall defer a decision on AZ's statute of limitations argument because I find the issue is dependent on factual determinations that can not be made at this stage of the proceedings. For the reasons that follow, I do not address BMS' statute of limitations argument because I dismiss the complaint on other grounds.

[6] This factual challenge is related to subject matter jurisdiction pursuant to 31 U.S.C. § 3732(a) (allowing false claims jurisdiction for any action under § 3730). If this court had jurisdiction over the federal claims pursuant

Argument 46.) In a factual attack, a court may consider matters outside of the pleadings. *United States ex rel. Atkinson v. Pa Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007). When a defendant does not challenge the facts alleged in the pleadings relating to jurisdiction, the court may accept those allegations as true. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). "A relator bears the burden of alleging facts essential to show jurisdiction under the False Claims Act as well as supporting those allegations with competent proof." *United States ex rel. Pritsker v. Sodexho, Inc.*, No. 03-6003, 2009 U.S. Dist. LEXIS 51469, *18 (E.D. Pa. Mar. 6, 2009) (internal quotations omitted).

2. Relator's Claims Against BMS Are Substantially Similar to Prior Public Disclosures

The FCA's public disclosure bar, 31 U.S.C. § 3730 (e)(4)(A), is intended "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" based on information already known to the government. *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1407 (2010). Under the public disclosure bar, a court lacks jurisdiction over a *qui tam* action when:

> (1) there was a 'public disclosure'; (2) 'in a criminal, civil, or administrative hearing, in a congressional, administrative or [GAO] report, hearing, audit, or investigation, or from the news media'; (3) of 'allegations or transactions' of the fraud; (4) that the relator's action was 'based upon'; and (5) the relator was not an 'original source' of the information.

United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 332 (3d Cir. 2005) (quoting 31 U.S.C. § 3730 (e)(4)(A)).

By its plain terms,§ 3730 (e)(4)(A) covers allegations or transactions disclosed in civil

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to § 3732(a), it would also have jurisdiction over the state law claims pursuant to § 3732(b).

hearings, which "encompass the full range of proceedings in a civil lawsuit," including the complaint. *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1156-57 (3rd Cir. 1991); see also *Paranich*, 396 F.3d at 334. An "allegation" of fraud means a "conclusory statement implying the existence of provable supporting facts." *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 653-54 (D.C. Cir. 1994). A relator's allegations are "based upon" the publicly revealed allegations or transactions if they are "supported by or substantially similar to the disclosed allegations and transactions." *Atkinson*, 473 F.3d at 519 (internal quotations omitted). The Third Circuit uses a formula to determine the amount of information necessary to trigger the public disclosure bar:

> If X+Y=Z, Z represents the allegation of fraud and X and Y represent its essential elements. . . . [I]f either Z (fraud) or both X (misrepresented facts) and Y (true facts) are disclosed by way of a listed source, then a relator is barred from bringing suit under § 3730(e)(4)(A) unless he is an original source.

Id. at 519.[7]

Here, both sets of the relator's claims against BMS– the kickback claims and the best price claims – are substantially similar to allegations and transactions that were already publicly disclosed when the relator filed his complaint.

a. Kickback Claims Against BMS

The relator's first set of claims against BMS involve allegations that in violation of

[7] The relator cites to *United States ex rel. Dunleavy v. County of Delaware,* 123 F.3d 734, 740 (3d Cir. 1997), noting a distinction between publicly disclosed "allegations or transactions" and the disclosure of ordinary "information." The relator relies heavily on this distinction in arguing that BMS conflates the two in its motion to dismiss. However, *Dunleavy* simply applies the same X+Y=Z formula for determining what quantum of information must be disclosed to trigger the public disclosure bar. *Id.* At 741.

anti-kickback laws BMS entered into sham rebate and data purchase agreements with Medco to induce it to purchase and dispense to government-plan patients the drug Coumadin, rather than the equivalent generic drugs. BMS has presented examples from various civil actions demonstrating that the allegations of fraud and the essential elements of relator's kickback claims had already been disclosed publicly when the relator informed the government of them prior to filing his original complaint in September 2003. These examples of public disclosures include the following:[8]

- In a civil action filed in March 1998 by a manufacturer of the generic equivalent for Coumadin against DuPont Merck Pharmaceutical Co. ("DMPC")[9], it was alleged that "DuPont Merck has offered and paid rebates and/or 'administrative fees' to . . . [pharmacy benefit managers] . . . to ensure that Coumadin, rather than [the generic equivalent drug], is dispensed to patients. No extra services were being rendered in exchange for the payment of these rebates and administrative fees by DuPont Merck." Complaint at ¶ 53, *Barr Labs, Inc. v. DuPont Merck Pharm. Co.*, No. 98-1795 (S.D.N.Y. Mar. 9, 1998).

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[8] BMS presented more than six civil actions with allegations and transactions similar to the relator's allegations here, along with numerous newspaper articles. I discuss three of those civil actions. The relator argues that all the essential elements of the fraud must be stated in a single public disclosure. However, the Third Circuit has not interpreted § 3730(e)(4)(A) in that way. *See, e.g. Atkinson,* 473 F.3d at 525-26 (essential element X disclosed in letter from Senate Chief Investigator; Y disclosed in newspaper article, government report, and FOIA response). The only case cited by the relator on this point, *United States ex rel. Foundation Aiding the Elderly v. Horizon West, Inc.,* No. 99-17539, 2001 U.S. App. LEXIS 27363 (9th Cir. Sept. 13, 2001), did not require a single public disclosure, but discussed "several documents purportedly disclos[ing] allegations of fraud" (*id.* at *8) and the Ninth Circuit applies the rule that "elements of fraud need not have been made public in a single document." *United States ex rel. Haight v. Catholic Healthcare West*, 445 F.3d 1147, 11521 n.1 (9th Cir. 2006).

[9] The relator's fourth amended complaint alleges that DuPont formed DMPC as a joint venture between DuPont and Merck & Co. and that DMPC eventually became BMS. (Fourth Am. Comp. ¶¶ 16, 83).

- A proposed class action suit filed in July 2003 alleged that BMS and other drug manufacturers conspired with Medco and other pharmacy benefit managers to "collect inflated prescription drug payments" by providing "rebates, hidden price discounts and/or other unlawful financial inducements" to encourage the use of their products, including the drug Coumadin. Amended Master Consol. Class Action Complaint at ¶¶ 2, 4, 327, 650, *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, No. 01-12257 (D. Mass. July 28, 2003).
- In a Medco ERISA Litigation suit filed in July 2002, the plaintiffs alleged that Medco entered into sham contracts with drug manufacturers that required the manufacturers to "pay kickbacks in the form of rebates, discounts and other soft dollars . . . . in exchange for Medco's discretionary decisions to provide access to, or to favor specific drugs on [] Medco's standardized formulary" and that those incentives were not disclosed. (First Amended Complaint at ¶¶ 4-5, *Jones v. Merck-Medco Managed Care, LLC*, No. 02-0707 (D. Nev. July 2, 2002). The plaintiffs also alleged that "Medco often decides to favor higher-cost drugs over lower-cost therapeutic equivalents." *Id*.

As these three examples show, the essential elements of the fraud – that BMS concealed the true nature of sham rebates with Medco (misrepresented facts) and that those rebates were meant to induce Medco to favor Coumadin over the equivalent generic drugs (true facts) – had already been alleged in numerous other civil actions.

It matters not that the publicly disclosed allegations and transactions do not identify the

exact theory of fraud alleged by the relator (violations under the False Claims Act) or the specific defendants, as long as there is sufficient information in the public sphere to put the government on notice of the potential presence of fraud. *In re Natural Gas Royalties Qui Tam Litig*., 566 F.3d 956, 961 (10th Cir. 2009) ("[A] disclosure need not identify a defendant by name to trigger the public disclosure bar, so long as the disclosures are 'sufficient to set the government on the trail of fraud as to [the] Defendants.'"); *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994) (finding that the FCA's jurisdictional bar is best understood as applying when publicly disclosed information has already, or can reasonably be expected to be, set the government "on the trail" of fraud); *see also United States ex rd. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997) ("A relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed."); *Sodexho, Inc.*, 2009 U.S. Dist. LEXIS 51469, at *27 ("[T]he FCA's jurisdictional bar would be rendered meaningless if a relator could bypass public disclosures through the semantic legerdemain of recasting disclosed . . . violations in false claims language."). Here, the many prior public disclosures were more than adequate to set the government "on the trail" of the fraud alleged by the relator.

The relator argues that the examples of public disclosures provided by BMS are merely allegations of widespread fraud among pharmaceutical benefit managers and major drug manufacturers that lack the specificity needed to implicate the FCA's public disclosure bar. However, the level of specificity necessary to trigger the bar is determined by the X+Y=Z

formula, which requires only public disclosure of the allegations of fraud or its essential elements. *Atkinson*, 473 F.3d at 519. While some of the sources presented by BMS include allegations of industry-wide fraud, other public disclosures, such as the examples above, repeatedly mention the BMS entities, Medco, and Coumadin, and allege that BMS entered into sham contracts with Medco to induce it to favor Coumadin over the equivalent generic drugs.

b. Best Price Claims Against BMS

The relator's second set of claims against BMS involve allegations that BMS submitted false best price reports for the drug Coumadin, causing overstated claims for reimbursement of Medicaid and 340B expenditures to be submitted to the government. Again, BMS has presented examples from various civil actions demonstrating that the allegations of fraud and the essential elements of relator's best price claims had already been disclosed publicly when the relator first filed a complaint with these claims in June 2009.[10] These public disclosures include the following:[11]

- The Medco ERISA Litigation filed in July 2002 included allegations that Medco "contracts with drug manufacturers to be paid moneys that the manufacturers will not be required to include in their best price submissions to the federal government" and that those incentives "include soft dollars, such as . . . data sales fees, or other indirect forms

[10] The relator's first mention of improper best price reports by BMS appear in the first amended complaint filed in November 2005. (First Am. Compl. ¶¶ 27-29.) The relator does not assert an actual claim against BMS under 31 U.S.C. § 3729(a)(7) based on alleged violations of BMS' best price reporting obligations until the third amended complaint filed in June 2009. (Third Am. Compl. ¶¶ 74, 232.)

[11] BMS again presented more than six civil actions with allegations and transactions similar to the relator's allegations, and I discuss three of those here.

of compensation that the manufacturers might provide to third parties, but which the manufacturers might not need to include when calculating their best price for the government." First Amended Complaint at ¶¶ 7 and 39*, Jones v. Merck-Medco Managed Care, LLC*, No. 02-0707 (D. Nev. July 2, 2002).

- In a civil action brought by the City of New York in August 2004 against defendants for their failure to comply with the Medicaid rebate statute, it was alleged that pharmacy benefit managers, including Medco, contracted with the defendants, including BMS, for product placement on formularies, which was "based on the profits they can make" including "rebates, and hidden discounts and financial incentives" that drug manufacturers "exclude[] from [their] calculations of Best Price." Complaint at ¶¶ 108, 114-15, 117*, City of New York v. Abbott Labs, Inc*., No. 04-6054 (S.D.N.Y. Aug. 4, 2004). The City alleged that BMS filed "intentionally false and misleading" average wholesale prices for specific drugs, including Coumadin. *Id.* at ¶ 262, Ex. A.
- A suit brought by the State of Montana in August 2003, related to *In re Pharm. Indus. Average Wholesale Price Litig*., MDL No. 1456, No. 01-12257 (D. Mass. July 28, 2003), alleged that defendants, including BMS, "did not report the actual Best Price," but instead "excluded discounts and other inducements . . . such as . . . rebates . . . that lower the providers' actual cost of the drugs, that resulted in lower prices reported to the Medicaid Program (and, consequently, the payment of lower rebates)." Second Amended Complaint at ¶ 612, *Montana v. Abbott Labs, Inc*., No. 02-09-H-DWM (D. Mont. Aug. 1, 2003).

These examples demonstrate that the relator's best price claims were also the subject of repeated prior public disclosures. The essential elements of the best price fraud – that BMS concealed the true nature of sham rebate and data purchase agreements with Medco (misrepresented facts) so that BMS could avoid accounting for those sham contracts in its best price reports to the government (true facts) – had already been alleged in numerous other civil actions and were sufficient to set the government on the trail of fraud before the relator filed a complaint with these claims. The relator may have blown a whistle here, but he was certainly not the first to toot.

3. Relator Is Not An "Original Source"

When a relator's claims are based upon publicly disclosed allegations or transactions of fraud, his claims are barred by the FCA's public disclosure bar unless the relator qualifies as an "original source." 31 U.S.C. § 3730(e)(4)(B); *Paranich*, 396 F.3d at 332.

> "'Original source' means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action . . . which is based on the information." 31 U.S.C. § 3730(e)(4)(B); *Paranich*, 396 F.3d at 335. "Direct knowledge is knowledge obtained without any intervening agency, instrumentality or influence: immediate", while "[i]ndependent knowledge is knowledge that does not depend on public disclosures." *Atkinson*, 473 F.3d at 520 (internal quotations omitted). A relator . . . cannot establish that he is an original source solely by relying on "unsupported, conclusory allegation[s]." *Kennard [v. Comstock Resources, Inc.]*, 363 F.3d [1039,] 1044 [(10th Cir. 2004)]. In assessing [the relator's] original source status, the Court must examine the allegations contained in the Amended Complaint. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473 (2007).

Sodexho, Inc., 2009 U.S. Dist. LEXIS 51469, at *40-41.

Here, the relator has failed to allege that he had the necessary direct and independent

knowledge of fraud by BMS to qualify as an "original source." The only facts alleged in the complaint relating to his direct and independent knowledge of the information on which his claims are based are recounting contract negotiations in which he participated but with no mention of how he obtained direct knowledge of the ultimate fraudulent conduct. (Fourth Am. Compl. ¶¶ 55, 86-87.) For example, the relator alleges that "he and other Medco personnel met on April 24, 2001 with DuPont personnel to negotiate an increase of the discount to 63% below the reported [wholesale acquisition cost]," and then baldly asserts that "it was DuPont's intent to disguise the . . . discount . . . to evade reporting these prices under the Best Price statute and provide kickbacks to Medco so that Coumadin would remain [Medco's] exclusive anticoagulant." (Fourth Am. Compl. ¶ 86.) However, it is not alleged how, when, where, or from whom he obtained the knowledge that the discounts given to Medco were somehow linked to the evasion of BMS' best price reporting obligations. The relator does not allege direct and independent knowledge of facts to establish FCA violations; rather, he merely alleges facts suggesting he had direct knowledge that BMS was selling Coumadin to Medco at a discount. I am left to guess how he obtained knowledge of fraud. The relator's reliance on inferences belies his claims that he has the direct and independent knowledge necessary to be deemed an original source.[12]

* * *

The relator's kickback claims and best price claims against BMS fail to overcome the

[12] The relator plainly alleges additional details about the circumstances of the fraud, but fails to allege how he himself obtained "direct and independent" knowledge.

FCA's public disclosure bar. The relator's claims against BMS are substantially similar to allegations and transactions that were already publicly disclosed before the relator asserted them, and the relator is not an "original source" because he fails to allege the necessary "direct and independent" knowledge. The relator has failed to meet his burden of alleging facts essential to demonstrate jurisdiction under the FCA and supporting those facts with competent proof. Accordingly, I must dismiss the relator's claims against BMS pursuant to Rule 12(b)(1) for lack of jurisdiction. Having dismissed all the federal claims against BMS, I decline to exercise supplemental jurisdiction over the state law claims.

The relator has had sufficient opportunities to cure jurisdictional deficiencies in his pleadings, specifically with regard to his "direct and independent" knowledge of the fraud. Therefore, I will dismiss the relator's claims against BMS with prejudice because I find that any amendments would be futile.

B. Relator's Claims Against AZ

AZ argues that the complaint must be dismissed under Rule 12(b)(6) for the relator's failure to satisfy the pleading requirements of Rule 9(b) and Rule 8(a). AZ argues that the relator has failed to plead the details of any actual false claim submitted by the states or any facts demonstrating that the states' submissions or AZ's best price reports were false. The allegations that form the basis for all counts against AZ are that (1) AZ provided illegal kickbacks in the form of rebates, service fees, disease-management fees, and unrestricted educational grants to Medco to induce it to purchase and dispense Prilosec and Nexium to government-plan patients, rather than the equivalent generic drugs,, which resulted in patients submitting claims with

overstated amounts to government plans for reimbursement; and (2) AZ failed to account for the sham agreements in its best price reports for Prilosec and Nexium, which resulted in AZ submitting false best price reports to the government, states submitting false claims for rebates under the Medicaid and 340B programs, and AZ underpaying its rebates. I find that the relator has pled the circumstances of the fraud with sufficient particularity to satisfy the pleadings requirements.

1. Standard of Review Under Rules 8(a) and 9(b)

Under Rule 12(b)(6), a complaint may be dismissed for failure to state a claim upon which relief can be granted. I must accept as true the factual allegations contained in the complaint and all reasonable inferences drawn therefrom and view the facts in the light most favorable to the plaintiff. Rule 8(a) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although Rule 8(a) does not demand "'detailed factual allegations,' . . . . 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id*. (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (quoting *Twombly*, 550 U.S. at 556).

Claims under the FCA sound in fraud and therefore must satisfy Rule 9(b)'s heightened pleading standard. *United States ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235, 242 n.9 (3d Cir.

2004). Under Rule 9(b), the complaint "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id*. Rule 9(b) requires this heightened pleading "in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Industrial Machinery Corp. v. Southmost Machinery Corp*., 742 F.2d 786, 791 (3d Cir. 1984).

2. FCA Claims Against AZ Are Stated With Sufficient Particularity

The "false claims" provision of the FCA imposes liability on a defendant who "knowingly . . . causes to be presented to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). The "reverse false claims" provision imposes liability on a defendant who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the government." 31 U.S.C. § 3729(a)(7). The falsity or fraud ascribed to these "false claims" and "reverse false claims" must be pled with particularity pursuant to Rule 9(b), so that the defendants are put on notice of the fraud being alleged by the relator.[13]

Here, the relator alleges that AZ and Medco set up an elaborate, well-planned scheme to defraud the government through a series of sham contracts. Specifically, the relator alleges the

[13] The "false claims" and "reverse false claims" provisions are the predicates for all the relator's counts against AZ.

details of eleven different agreements between AZ and Medco that he says were intended to carry out their plan to defraud the government. These details include contract titles, payment amounts, the products involved, and the years during which these fraudulent agreements were in force. The relator alleges meeting dates and the names of participants; in short, the how, when, and why the fraudulent agreements were created.

The relator then alleges that as a consequence, government-plan patients and states were caused to submit inflated and therefore "false claims" for payments and that AZ submitted "reverse false claims" to avoid its refund obligations. The alleged "false claims" submitted by government-plan patients were "false" only in the sense that the claims were based on the alleged kickback fraud between AZ and Medco; similarly, the alleged "false claims" submitted by the states were false only in the sense that they were based on the alleged false best price reports submitted by AZ. The falsity of the "reverse false claim" lies in AZ's alleged failure to account for its sham agreements with Medco in its best price reports. The relator has therefore alleged with sufficient particularity, as required by Rule 9(b), the circumstances of the falsities and fraud in its FCA claims against AZ.

AZ argues that the relator's claims must fail because he has not identified and pled the details of any actual false claim. However, "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *U.S. ex el. Lemmon v. Envirocafre, Inc*., No. 09-4079, 2010 U.S. App. LEXIS 16117 *21 (10 Cir. 2010). Requiring the relator to plead the details of an actual claim would not place AZ in a better position to answer and defend the charges of fraud

against it. Here, the "false claims" are only false because they are based on the kickback fraud between AZ and Medco or the "false" best price reports submitted by AZ. If the relator had described the details of an actual claim submitted by a government-plan patient or state Medicaid office and included specifics, such as the contents of the claim, who submitted it, the date, the amount claimed, and the amount actually due, AZ would not be in a better position to defend itself because neither the patients nor the states are being charged with fraudulent conduct.[14] A case should not turn on whether a pointless allegation has been pled or not.

Furthermore, "allegations of 'date, place, or time'" may fulfill the requirement of particularity, "but nothing in Rule 9(b) requires them." *Seville*, 742 F.2d at 791. Here, AZ "use[d] alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.*

a. Kickback Claims Against AZ

The fourth amended complaint is littered with details about the alleged kickbacks which form the basis of the false claims, such as the specific rebates, service fees, disease-management fees, and unrestricted educational grants. (Fourth Am. Compl. ¶¶ 123-230.) The relator alleges the parties involved, (AZ and Medco), the drugs at issue, (Prilosec and Nexium), the dates the kickbacks were paid (from 1996 through at least 2003), the dates of certain meetings where the sham agreements were discussed (e.g., Fourth Am. Compl.¶ 124), and the names of persons at those meetings (e.g., Mark Mallon, Carrie Maglich and Mark Bardi). *Id.* The relator then

[14] In its motion to dismiss, AZ does not specifically address the deficiencies in the alleged "false claims" submitted by government-plan patients, but instead focuses on the "reverse false claims" submitted by AZ in connection with its best price reporting obligations and the "false claims" submitted by the states as a result of the false best price reports.

alleges that these kickbacks resulted in patients submitting inflated, and thereby false, claims to government plans for reimbursement: "These kickbacks were intended to result in the dispensing of these drugs and reimbursement by Medco's customers, including Government Programs, when using Medco's mail service pharmacies, including under the FEHBP contract with Medco." (*Id.* ¶ 239.) This is enough to put AZ on notice of the circumstances of the fraud.

b. Best Price Claims Against AZ

Similarly, AZ argues that the relator's best price report claims must fail because the relator has no personal knowledge of the content of any actual best price reports. However, AZ appears to conflate Rule 9(b)'s particularity requirement with the FCA's requirement that the relator have "direct and independent" knowledge of the fraud if there are prior public disclosures. *See* 31 U.S.C. § 3730(e)(4)(B). The relator is not required to plead "direct and independent" knowledge to satisfy Rule 9(b). He must only plead the circumstances of the fraud itself so that AZ can understand the nature of the claims against it and is protected against spurious charges. *See Seville*, 742 F.2d at 791.

As described above, the relator has sufficiently alleged the details of fraud involving the sham agreements between AZ and Medco. The relator then alleges that AZ "submitted false quarterly statements to [the government] of its Best Prices on [Prilosec and/or Nexium] to reduce improperly its rebate obligations to the States under the Best Price Program" by not accounting for those agreements. (*Id.* ¶ 141; *see also, id.* ¶¶ 151, 163, 171, 184, 187, 193, 204, 214, 221, 229, 237.) The relator also alleges that AZ's "false quarterly statements of the Best Prices on [Prilosec and Nexium] caused the States to submit false and inflated submissions to the Federal

Government for reimbursement of Medicaid expenditures." (*Id*.) Again, the relator alleges the parties involved in the underlying fraud, the drugs at issue, and the periods the false best prices were reported. With these allegations, AZ is placed on sufficient notice of the charges against it.

* * *

The relator's kickback claims and best price claims against AZ satisfy the pleading requirements of Rules 8(a) and 9(b). Requiring the relator to plead an actual claim in these circumstances would not place AZ in a better position to answer and defend the charges of fraud against it. The relator's FCA claims against AZ are pled with sufficient particularity to place AZ on notice of the charges and protect it from spurious charges. Accordingly, I must deny AZ's motion to dismiss the relator's claims.

IV. CONCLUSION

For the foregoing reasons, I have granted BMS' motion to dismiss under Rule 12(b)(1) for lack of jurisdiction, and I have denied AZ's motion to dismiss under Rule 12(b)(6) for failure to state a claim. I dismissed all of the relator's claims against BMS with prejudice because I find that the any amendments would be futile.

BY THE COURT:

/s/ J. William Ditter, Jr.
J. WILLIAM DITTER, JR., S.J.